UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE: KIND LLC "HEALTHY AND ALL NATURAL" LITIGATION	15-MD-2645 (WHP) 15-MC-2645 (WHP)
This Document Relates to: ALL ACTIONS	Hon. William H. Pauley III, presiding

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO LIFT STAY

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Regulations & Executive Orders

INTRODUCTION

In September of last year, this Court stayed Plaintiffs' claims based on their allegations that Defendant falsely labeled its snack foods as "all natural," because at that time it appeared that the Food and Drug Administration ("FDA") was poised to issue a rule regarding use of the term "natural" on food labels. (Dkt. 83 (the "September 2016 Order") at 14.) However, since the FDA's public comments period closed on May 10, 2016 — more than a year ago —the FDA has done absolutely nothing regarding promulgation of any such rule. The FDA never stated it *would* issue such a rule. Moreover, in light of President Trump's election and subsequent promulgation of executive orders dramatically curtailing the ability of agencies such as the FDA to issue new regulations and, instead, shifting the focus to elimination of regulations, it is highly unlikely that the FDA will issue any such rule under this administration.

Since the Court first analyzed the issue in its September 2016 Order, President Trump was elected and quickly instituted sweeping changes designed to reduce the amount of federal regulations and the overall size of the federal government. He initially froze and then placed stringent restrictions on government hiring, promulgated several executive orders that dramatically curtail the power of agencies such as the FDA to issue new regulations, and announced a budget for 2018 that would slash that agency's funding and, by extension, its ability to issue any new regulations regarding use of the term "natural" on food labels under the new, dramatically curtailed regulatory regime.

Furthermore, *if* the FDA eventually issues new rules, they will not retroactively affect Plaintiffs' claims insofar as they are based on Defendants' past conduct, which preceded any such regulations.

In light of these events, analysis of the factors informing application of the primary jurisdiction doctrine now results in a far different conclusion than it did in September 2016, as shown below. Accordingly, Plaintiffs respectfully request that the Court lift the stay on their "all natural" claims.

ARGUMENT

I. EFFICIENCY MUST GUIDE THE COURT'S APPLICATION OF THE PRIMARY JURISDICTION DOCTRINE

The Court stayed Plaintiffs' "all natural" claims under the primary jurisdiction doctrine. (Dkt. 83 at 7-11.) The Court was guided by the Second Circuit's opinion in *Ellis v. Tribune Television Co.*, 443 F.3d 71 (2d Cir. 2006). There, the Second Circuit reasoned that "[n]o fixed formula exists for applying the doctrine of primary jurisdiction," but described four factors to "generally" guide lower courts in their analysis "on a case-by-case basis." *Id.* at 82 (citations omitted). Those four factors are:

> (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise;
>
> (2) whether the question at issue is particularly within the agency's discretion;
>
> (3) whether there exists a substantial danger of inconsistent rulings; and
>
> (4) whether a prior application to the agency has been made.

Ellis, 443 F.3d at 82-83.

"'The . . . doctrine is rooted in part in judicial efficiency.'" (Dkt. 83 at 6 (quoting *United States v. Philip Morris USA Inc.*, 686 F.3d 832, 838 (D.C. Cir. 2012)).) Thus, "not every case that implicates the expertise of federal agencies warrants invocation of primary jurisdiction." *Astiana v. Hain Celestial Group, Inc.*, 783 F.3d 753, 760 (9th Cir. 2015). "Rather, the doctrine is

reserved for a 'limited set of circumstances' that 'require[] resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency.'" *Martin v. Tradewinds Beverage Co.*, No. 16-9249, 2017 WL 1712533, *3 (C.D. Cal. April 27, 2017) (citation omitted).

Courts "should 'balance the advantages of applying the doctrine against the potential costs resulting from complications and delay in the administrative proceedings.'" (Dkt. 83 at 7 (quoting *Ellis*, 443 F.3d at 83).) "[C]ourts must . . . consider whether invoking primary jurisdiction would needlessly delay the resolution of claims," and "'efficiency' is the 'deciding factor' in whether to invoke primary jurisdiction." *Astiana*, 783 F.3d at 760 (quoting *Reid v. Johnson & Johnson*, 780 F.3d 952, 967-68 (9th Cir. 2015)).

A district court has discretionary power to stay proceedings. *See Landis v. North American Co.*, 299 U.S. 248, 254 (1936)). However, "if there is even a fair possibility that the stay for which [the movant] prays will work damage to someone else," there must be "a clear case of hardship or inequity in being required to go forward." *See Landis*, 299 U.S. at 255. As Plaintiffs' claims have merit, consumers are continuing to be harmed by Defendants' deceptive labeling.

In light of the facts that (1) the FDA has made no progress toward issuing any regulation or other ruling regarding the use of "natural" on food labels; (2) the new administration's regulatory reform agenda that calls for dramatically cutting existing regulations — not creating new ones; (3) that any new regulations will not apply retroactively to Defendants' past unlawful conduct; and (4) the harm that continues to befall consumer due to Defendant's deceptive labeling, no efficiency can be gained from a further stay of these proceedings.

A. The Issues Before the Court Are Within the Conventional Experience of Judges

As this Court recognized when it implemented the stay, the first factor enunciated by *Ellis* and other courts counsels against staying these proceedings. (Dkt. 83 at 8-9.) Since the Court's September 2016 Order, a number of other district courts have refused to stay, or lifted stays on, analogous proceedings based on allegations of false "natural" labels on food products under the primary jurisdictions doctrine. *See, e.g.*, *Tradewinds Beverage Co.*, 2017 WL 1712533, *3 (C.D. Cal. April 27, 2017) (denying motion to dismiss based on primary jurisdiction doctrine where plaintiff alleged defendant falsely labeled tea products "all natural"); *In re Hain Celestial Seasonings Prod. Consumer Litig.*, No. 13-1757 (Dkt. 315-317) (C.D. Cal. Nov. 7, 2016) (lifting stay imposed under primary jurisdiction doctrine after six months and no indication that the FDA had taken any rulemaking or informal guidance action on the question of "natural" food labeling).

B. The Question at Issue Is Not Particularly Within the Agency's Discretion

At the time the Court implemented the stay, it reasoned that this factor favored application of the primary jurisdiction doctrine because it then appeared that "the FDA seems to be prepared to address core issues in this case, including what types of processed foods may be labeled 'natural' and whether genetically engineered foods may be labeled 'natural.'" (Dkt. 83 at 9.) However, this appears to no longer be the case.

The day he took office, President Trump issued a "Memorandum for the Heads of Executive Departments and Agencies,"[1] which ordered its recipients to "immediately" cease issuing any new regulations, and to withdraw any then awaiting publication in the Federal

[1] *Available at* <https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies> (last visited June 26, 2017).

Register, with only a narrow exception for "emergency situations." Soon afterwards, on January 30, 2017, the President issued his "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs," which *inter alia* required that, "for every one new regulation issued, at least two prior regulations be identified for elimination." Executive Order 13771, *available at* <https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling> (last visited June 26, 2017). That Executive Order was followed with another the next month, which requires each federal agency to establish a task force with the goal of "identifying regulations for repeal, replacement, or modification." Executive Order 13777, § 3(g), *available at* <https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda> (last visited June 26, 2017). Needless to say, neither that executive order nor any of the President's other executive orders or memoranda create any incentive for the FDA or any other agency to promulgate new regulations or otherwise address "natural" food labeling.

In addition to the requirement that agencies submit their suggested rule cuts to the White House before issuing any new regulations, the FDA is unlikely to have any budget for new rules this fiscal year, which closes at the end of September. *See generally*, Emily Field, *FDA, Industry Face Hurdles With Trump Regulatory Overhaul* (Law360 Jan. 30, 2017), *available at* <https://www.law360.com/articles/886162/fda-industry-face-hurdles-with-trump-regulatory-overhaul> (last visited June 26, 2017).

And the President's proposed budget for 2018 is more grim. It anticipates a reduction in the budget allocated to the Department of Health and Human Services, which includes the FDA, of at least 16.2%. *See* OMB, Budget of the U.S. Government: A New Foundation For American Greatness, Fiscal Year 2018, at 42, *available at* <https://www.whitehouse.gov/sites/

whitehouse.gov/files/omb/budget/fy2018/budget.pdf> (last visited June 26, 2017); Federal News Radio, *2018 Budget Highlights: A Breakdown of What Civilian Agency Programs Are Up, Down* (March 16, 20107), *available at* <https://federalnewsradio.com/budget/2017/03/2018-budget-highlights/> (last visited June 26, 2017) (calculating figure at 17.9%, accounting for increase in funding for Health Care Fraud and Abuse Control).

Not only is the FDA prohibited from issuing any new regulation regarding food labeling without eliminating at least two others, and working with an inadequate and shrinking budget, but it is likely understaffed. Soon after taking office the President implemented a hiring freeze across the entire federal government. The freeze was supplanted by guidance from the Office of Management and Budget ("OMB") which generally seeks to limit the size of the federal government and to reduce the number of employees within agencies such as the FDA. OMB, *Memorandum for Heads of Executive Departments & Agencies* (M-17-22, April 12, 2017), *available at* <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-22.pdf> (last visited June 26, 2017). Thus, if "priority food public health and safety matters" were previously "largely occupying the limited resources that FDA has to address food matters" such that it declined to address the issue of "natural" food labels when asked to do so by several courts during the last administration, it is unlikely to have sufficient resources to address the issue now. *Astiana*, 783 F.3d at 761 (quoting Letter from Department of Health & Human Services, *In Re Gen. Mills*, No. CIV–A–12–249, at ECF No. 94).

In sum, while the FDA has the power to issue a regulation governing "natural" food labeling, it is unlikely to do so under the current administration. Meanwhile, this Court is

perfectly capable of deciding the issues before it, and Plaintiffs are prejudiced by continued delay.

C. There Is No Danger of Inconsistent Rulings

The Court previously reasoned that this factor weighed in favor of a stay because the FDA might issue a regulation or guidance as to whether a particular ingredient can or cannot be considered "natural." (Dkt. 83 at 10-11.) Because, as explained above, the changed circumstances suggest that no new regulation will issue, and the FDA is understaffed and under-budgeted; accordingly, there also is less danger of any inconsistency between any ruling of this Court and such FDA action.

Furthermore, regardless of what the FDA may do in the future, the relevant question for purposes of this lawsuit is whether a reasonable consumer would understand Defendant's use of the term "natural" to include the unnatural ingredients described in the Amended Complaint when he or she bought Defendant's products, prior to the FDA taking any further action. *See, e.g.*, *Brazil v. Dole Packaged Foods, LLC*, 660 Fed. Appx. 531 (9th Cir. 2016) (reversing summary judgment for defendant in "all natural" case, observing that such claims under consumer protection laws "are evaluated from the perspective of a reasonable consumer," and ruling that "[t]he district court's decision not to stay or dismiss this case under the doctrine of primary jurisdiction was not an abuse of discretion"). As the FDA itself observed when requesting comments, survey evidence "suggests that nearly two-thirds of U.S. consumers are currently misled by use of the term 'natural,'" and "64% think [the label means] no GMOs were used." 80 FR 69905-01, at 69907.

There is no danger of inconsistent rulings with regard to this issue, which concerns consumers' past understanding of the term "natural" when they bought the products at issue in

this case. No rule that the FDA may issue, under this or some future administration, could retroactively make Defendant's use of the term "natural," as alleged in the Amended Complaint, any less deceptive or less actionable at that time. That is, even if the FDA issued a rule that specifically allowed food producers to include synthetic and toxic ingredients in foods labeled "natural," going forward, such a rule could not affect their prior understanding that the term meant something very different when they purchased Defendant's products.

D. The Prior Application to the FDA No Longer Appears Likely to Result in Issuance of a Rule by the FDA

The Court previously concluded that the final *Ellis* factor counseled in favor of a stay because the FDA had then "initiated proceedings based on applications from citizen petitions and 'three Federal district courts' seeking guidance on whether certain products 'may be labeled as "Natural," "All Natural," and/or "100% Natural."' 80 FR 69905-01, 2015 WL 6958210." (Dkt. 83 at 11.) Because, as explained above, it no longer appears that the agency is focused on this issue or on promulgating any new regulations, this factor no longer weighs in favor of a stay. Rather, continued implementation of the stay will only prejudice Plaintiffs.

E. Plaintiffs Are Prejudiced by Continued Delay

As this Court recognized when it implemented the stay at issue, it must "'balance the advantages of applying the [primary jurisdiction] doctrine against the potential costs resulting from complications and delay in the administrative proceedings.'" (Dkt. 83 at 7 (quoting *Ellis v. Tribune Television Co.*, 443 F.3d 71, 83 (2d Cir. 2006)). The delay has become prejudicial, and if it is going to continue until the FDA takes some action on its rulemaking process, the delay could be indefinite. Nothing has happened in over a year since the comment period closed, or in

the nine months since this Court implemented the stay. As the stay continues, evidence grows stale, witnesses' memories will fade, and Defendant's employees will leave or retire.

Plaintiffs previously illustrated for the Court how difficult and lengthy the process for issuing any new regulation regarding labeling of food as "natural" would have been, before the current administration's "regulatory reform agenda"[2] took effect. In this regard, Plaintiffs referenced the "Reg Map" that was in effect under the prior administration. (Dkt. 91-1.) As shown there, prior to President Trump's executive orders, the rulemaking process consisted of some nine steps, including soliciting input from external groups, and the FDA never appeared to get past the first of these steps before President Trump took office. (Dkt. 91 at 2.) Under the prior regulatory regime, for example, it took more than six-and-a-half years for the FDA to publish final guidance regarding use of the term "evaporated cane juice" after it first published draft guidance on the subject. (*Id.* (citing FDA, *Ingredients Declared as Evaporated Cane Juice: Guidance for Industry*, available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM502679.pdf> (last visited Dec. 14, 2016)).)

Moreover, existing laws regarding Plaintiffs' natural claims at issue in this matter apply to Defendants' past conduct. *See Boelter v. Hearst Commc'ns, Inc.*, 192 F. Supp. 3d 427, 438 (S.D.N.Y. 2016) ("Retroactivity is not favored in the law.") (citing *Landgraf v. USI Film Prods.*, 511 U.S. 244, 264, 114 S. Ct. 1483, 128 L.Ed.2d 229 (1994); *see also Stout v. Int'l Bus. Machines Corp.*, 798 F. Supp. 998, 1001 (S.D.N.Y. 1992) (stating the same). Therefore, the likelihood of any FDA regulation clearing Defendants of liability for their past unlawful conduct is minimal at best.

[2] Executive Order 13777, *supra*.

Although it recognized the risk of prejudicial delay in its September 2016 Order, the Court then reasoned that the stay nonetheless was justified "because the FDA has already completed its notice and comment period and seems determined to address the 'all natural' labeling issue." (Dkt. 83 at 12.) More than a year has now passed since that notice and comment period closed, the FDA has taken no action on this issue, and it appears unlikely to do so. It is time to lift the stay.

CONCLUSION

For all these reasons, Plaintiffs respectfully request that the Court lift the stay it imposed on this action, and allow Plaintiffs to proceed.

Respectfully submitted,

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